

Meeting

- Decision from Ninth Circuit Court
- Upcoming briefing
- Biweekly meetings
- Program review

So last week, on Earth Day, the Ninth Circuit Court issued their decision to NRDC's lawsuit that was filed last summer against the agency for unreasonable delay in responding to their 2009 petition to cancel all pet products containing TCVP.

The Court ordered the agency to respond to the petition by either denying it or granting it within 90 days. OPP is assuming that the clock has started running and we are working to issue a response by July 21. We've also been working on a desk statement for any press inquiries. As of Monday, it was with the OCSPP IO for review. FEAD has told us that they will let us know once it has been cleared by the Office of Public Affairs.

The only registrant for the TCVP pet products in Hartz. We spoke with them on Friday and they said { **Ex. 5 Deliberative Process (DP)** }

We are looking to brief Rick and likely Alex as early as next week or the following week on the risk picture. HED I will hand it over to you in just a minute for an update. After today and similar to chlorpyrifos we are probably going to schedule biweekly team meetings as we prepare the response and move forward with reg review.

Program review is tomorrow. PRD will be presenting most of TCVP but we've asked HED to deliver their talking points. And with that I'm going to hand it over the HED for their updates and then we can talk about preparing for the briefing.

Kelly from HED

- Late last year
- Reviewed and incorporate studies from hartz

Risks

- residential ORE side
- still have some risk estimates that are below the LOC of 1000
- presenting literature study and new TC study
- risk estimate range from 120 to above 1000
- depending on the size of the collar

All of the trigger pump sprays do not have risks of concern

- refinements to dietary assessment

% PADs above, can't do steady state aggregate

Cancer aggregate – those numbers across all pet products = 10^{-5} and 10^{-7} , some are below the 10^{-6} mark

Ex. 5 Deliberative Process (DP)

Would need to know the ground for denying/granting by <ay 13 (three weeks from the court decision).

- need to get working on the notice of intent to cancel

DV asked – has the OGC IO met with OCSPP IO about the timeframe so that we should be clear on what we should be working on

Tetrachlorvinphos DRA

Current Status

- Tetrachlorvinphos (TCVP) is an organophosphate (OP) insecticide used to control fleas, ticks, various flies, lice, and insect larvae on livestock and domestic animals and their premises. TCVP is also applied as a perimeter treatment.
- There are no registered crop uses for TCVP. All agricultural uses were cancelled around 1987
- Residential uses include pet collars, flea and tick powder, pump sprays for pets.
- The ecological risk assessment was completed September 22, 2015. OCSPP intends to finalize a revised human health DRA in June 2020 to include additional registrant data provided in August 2019.
- In April 2009, the Natural Resource Defense Council (NRDC) petitioned the EPA to cancel all TCVP pet products citing risks to toddlers from hand-to-mouth exposure from residential pet-care uses. A revised human health risk assessment was issued in 2016. EPA responded that it would address pet-care uses in registration review.
- In May 2019, NRDC filed a petition with the Ninth District Court for an “unreasonable delay” on EPA’s part to respond. Oral arguments were held in early February 2020 and a Court decision is pending.
- Publication Target and potential 60-day comment period may depend on when the Court makes a decision. At this time, OCSPP intends to publish the revised human health DRA on or before July 31, 2020.

Key Points

- Residential risks stemming from pet uses

- There are limited alternative pet collars to replace TCVP collars.
- Court decision may impact timeframe for comment period and Proposed Interim Decision

Human Health Risk Assessment Conclusions

- The revised human health DRA is presenting risk estimates with the 10X FQPA Safety Factor/Database Uncertainty Factor.
- The initial DRA identified potential dietary, residential, and occupational non-cancer risks depending on the LOC):
 - Dietary risks anticipated to be primarily a result of drinking water pending review of dietary inputs.
 - Some residential post-application margins of exposure (MOEs) are of concern for certain pet collars and pet dust products, depending on the LOC.
 - Residential post-application risk estimates for pet collars are as refined as possible, utilizing a submitted dust torsion study for the ratio of liquid/dust in the TCVP pet collar products and two chemical-specific transferable residue studies.
 - Some occupational handler MOEs are of concern for certain handheld equipment scenarios, fogging scenarios, and dust products depending on the LOC.
 - Some occupational handler risk estimates could be mitigated with the addition of PPE (i.e., a PF10 respirator), but some scenarios still remain a concern with maximum PPE.
- Cancer risk estimates have also been estimated for TCVP with potential risks identified for residential post-application exposure and occupational handler exposure
- HED cannot make aggregate safety finding based on potential dietary and residential risks.

Ecological Risk Assessment Conclusions

- Residues can pass through livestock and remain active in manure.
- The ecological DRA identified risks to birds, mammals, and freshwater invertebrates.
- DRA did not quantify risks to terrestrial invertebrates; however, based on available data terrestrial invertebrate risk.
- Single incident with bird categorized as highly probable.
- Tier 1 suite of laboratory-based studies of honey bees incomplete; missing acute/chronic oral toxicity for adult and larval bees.
- In March 2016 during 60-day comment period, EPA received comments on the EFED DRA from the United States Dept. of Agriculture (USDA), Bayer (registrant), and Centers for Biological Diversity (CBD) that are addressed in the EPA's "*Response to Comments on the Preliminary Ecological Risk Assessment for Tetrachlorvinphos (TCVP)*".

Communications

- No rollout is proposed; OCSPP/OPA will have a desk statement on-hand for any press inquiries.
- Some press is possible due to ongoing litigation.

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Key Points

- Residential risks stemming from pet uses
 - There are limited alternative pet collars to replace TCVP collars.
 - Court decision may impact timeframe for comment period and Proposed Interim Decision
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- The human health DRA is presenting risk estimates both with and without the 10X FQPA Safety Factor/Database Uncertainty Factor.
 - Dietary, dermal and incidental oral exposures level of concern (LOC): 100 or 1000
 - Inhalation exposure LOC: 30 or 300
 - DRA identified potential dietary, residential, and occupational non-cancer risks depending on the LOC:
 - Dietary risks anticipated to be primarily a result of drinking water pending review of dietary inputs.
 - Some residential post-application margins of exposure (MOEs) are of concern for certain pet collars and pet dust products, depending on the LOC.
 - Residential post-application risk estimates for pet collars are as refined as possible, utilizing a submitted dust torsion study for the ratio of liquid/dust in the TCVP pet collar products and two chemical-specific transferable residue studies.
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- Some occupational handler risk estimates could be mitigated with the addition of PPE (i.e., a PF10 respirator), but some scenarios still remain a concern with maximum PPE under both LOC scenarios.
- Cancer risk estimates have also been estimated for TCVP:
 - Dietary range: [] (pending)
 - Residential handler range: [Ex. 5 Deliberative Process (DP)]
 - Residential post-application range: [Ex. 5 Deliberative Process (DP)]
 - Occupational handler range: [Ex. 5 Deliberative Process (DP)]
- Cannot make aggregate safety finding based on potential dietary and residential risks.

Ex. 5 Deliberative Process (DP)

Ecological Risk Assessment Conclusions

- Residues can pass through livestock and remain active in manure. [[HYPERLINK](#) "file:///C:/Users/pbiggio/AppData/Local/Microsoft/Windows/NetCache/Content.Outlook/N5F1EP70/Tetrachlorvinphos%20Q3%20DRA%20Summary_040120(tms).docx" \ | "_msocom_1"]
- The ecological DRA identified risks to birds (chronic RQs: 0.5 – 87), mammals (acute RQs <0.1 – 9.2; chronic RQs 0.05 – 8.35), and freshwater invertebrates (acute RQs 0.34 – 0.8; chronic RQs 5 – 9).
- DRA did not quantify risks to terrestrial invertebrates; however, based on available data terrestrial invertebrate risk (adult acute contact RQ 0.078 – 0.77).
- Single incident with bird categorized as highly probable.
- Tier 1 suite of laboratory-based studies of honey bees incomplete; missing acute/chronic oral toxicity for adult and larval bees.

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